



Association of Community Cancer Centers

October 11, 2022

The Honorable Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Inspections of Manufacturing Facilities

Dear Commissioner Califf:

The Association of Community Cancer Centers (ACCC) is the leading education and advocacy organization for the multidisciplinary cancer care community, representing more than 30,000 cancer care professionals from over 1,700 private practices, hospital-based cancer programs, large healthcare systems, and major academic centers across the country. ACCC members care for millions of patients and families in the fight against cancer, and our organization brings these professionals from across oncology disciplines together to promote and advocate for access to affordable, high-quality, and equitable cancer care.

One vital aspect of delivering high-quality cancer care is having access to the latest therapies. Unfortunately, due to COVID-19 and workforce shortages, we have seen interruptions in the approval of breakthrough therapies due to inspection delays. While we appreciate the critical role of the U.S. Food and Drug Administration (FDA) in ensuring that these novel therapies are safe and effective, we are concerned that delays in manufacturing facility inspections can unnecessarily impede patient access to these new treatments.

Delays in the approval process for novel therapies are especially concerning when they impact diseases for which there are currently no FDA approved treatments available, which is the case for some rarer forms of cancer. For patients with these rare and aggressive tumor types, time is of the essence, and inspection delays can have serious, irreversible consequences for patients desperately awaiting treatment. Additionally, we are concerned when these delays impact disease states with a disproportionate incidence among minority communities. We fear that such delays can exacerbate existing racial and ethnic disparities in cancer treatment and outcomes. Does the FDA have a plan to ensure that inspections impacting these high priority therapeutic areas and historically underserved patient populations receive the prioritization they deserve?

ACCC remains grateful for the work of the FDA in ensuring patients have access to innovative medications and treatments. As this work continues, we hope the FDA will utilize every tool and resource at its disposal to ensure that novel cancer therapies, particularly those that address unmet needs and disproportionately impact minority communities, are given priority attention. If you have any questions or would like to discuss in further detail, please contact Matt Devino at mdevino@acc-cancer.org or (301) 263-3510.

Respectfully,

A handwritten signature in black ink that reads "Christian G. Downs". The signature is written in a cursive, flowing style.

Christian G. Downs, JD, MHA
Executive Director
Association of Community Cancer Centers (ACCC)